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Attorney Docket No. 0884

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dhugga et al. Date: August 1, 2002
Serial No.: 09/374,967 Group Art Unit: 1635
Filed: August 16, 1999 Examiner: Mary M. Schmidt
For: Compositions and Methods for Manipulating Gum Production in Plants

Assistant Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL OF APPEAL BRIEF

Transmitted herewith in triplicate is the Appeal Brief in this application with respect to the Notice of Appeal filed on June 3, 2002.

Pursuant to 37 C.F.R. §1.17(c) the fee for filing the Appeal Brief is \$320.00. Please charge \$320.00 to Deposit Account No. 16-1852. A duplicate copy of this transmittal is attached. The Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. §1.16 and §1.17 which may be required by this paper, or credit any overpayment to our Deposit Account No. 16-1852.

Respectfully submitted,

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Anthony L. Duggan
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APPEAL BRIEF

Real Party in Interest

The subject application is owned by Pioneer Hi-Bred International, Inc. of Des Moines, Iowa.

Related Appeals and Interferences

To the best of my knowledge there are no related appeals or interferences that will directly affect or be directly affected by, or have a bearing on, the Board of Appeals decision in the pending appeal.

Serial No. 09/374,967
Group Art Unit: 1635

Status of Claims

Claims 1, 3-5, 7-13, 23, 24, 32, 33, and 41-45 are in the application for consideration. Claims 2, 6, 14-22, 25-31, 34-40, 46, and 48-76 were cancelled without prejudice. No claims are allowed.

Status of Amendments

The amendment after final was entered.

Summary of the Invention

Gums are derived from the seeds of plants which synthesize and accumulate certain polysaccharides as storage polymers.

Because they are capable of forming gels or highly viscous solutions at high concentrations, gums have many applications in processing and industry.
(Specification, page 1, lines 12-23 and page 2, lines 1-5)

There are two classes of seed-derived gums: galactomannans and xyloglucans. (Specification page 2, lines 11-12). Of the two, galactomannans are more commonly used and more desirable.

Gums are currently prepared from bacteria or extracted from the seeds of sub-tropical plants. Because current methods are expensive, it is desirable to develop crop plants which over-produce galactomannan gum. The present invention provides compositions for the over-expression of enzymes and substrates required for the synthesis of galactomannan gum.

Issues

Claims 1, 3-5, 7-13, 23, 24, 32, 33, and 41-45 are rejected under 35 USC §112, first paragraph, for lack of written description and scope of enablement.

Grouping of the Claims

The claims do not stand or fall together. The patentability of the claims will be argued separately.

Arguments

The First Paragraph of Section 112 Rejection of Claims 1, 3-5, 7-13, 23, 24, 32, 33, and 41-45 for lack of written description

Claims 1, 3-5, 7-13, 23, 24, 32, 33, and 41-45 are rejected under 35 USC §112, first paragraph for lack of written description.

The examiner cites MPEP 2163 IA: "The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function."

The examiner states: "In the instant case, the claims as amended read on any maize or leguminous plant GDP-mannose pyrophosphorylase ... the function of GDP-mannose pyrophosphorylase, does not clearly describe the sequence of the claimed nucleic acids encoding such a protein so that one skilled in the art would be able to envision Applicant's claimed invention"

The metes and bounds of the presently claimed invention are described both functionally and structurally, not merely by a method of making coupled with function.

First, the claimed invention is described by reference to the function of the sequence: the claimed sequences must function as a plant GDP-mannose pyrophosphorylase as recited in the specification on page 4, lines 15-17: "The formation of the substrate GDP-mannose, from mannose-1-phosphate and GTP, is catalyzed by the enzyme GDP-mannose pyrophosphorylase." And again on page 7, lines 13-15: "Thus, for purposes of the present invention, a functionally equivalent

variant of GDP- mannose pyrophosphorylase will catalyze the formation of GDP-mannose, from mannose-1-phosphate and GTP."

Next, the application discloses the claimed nucleic acids structurally by "having at least 90% identity" to a nucleotide identified functionally as a plant GDP-mannose pyrophosphorylase, or to a nucleotide having the nucleotide sequence of SEQ ID NO:1, or to a nucleotide encoding the amino acid sequence of SEQ ID NO: 2.

Finally, the claimed invention is described physically/chemically as "a nucleotide sequence that hybridizes ... under stringent conditions" to a nucleotide identified functionally as a plant GDP-mannose pyrophosphorylase, or to a nucleotide having the nucleotide sequence of SEQ ID NO:1, or to a nucleotide encoding the amino acid sequence of SEQ ID NO: 2. Physical and chemical properties associated with the claimed sequences are defined by hybridization conditions to the disclosed sequence on pages 10 of the specification, line 23, through page 12, line 13; and by percent identity to the disclosed sequence described on page 12, lines 14-29.

The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "*reasonably* conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." (MPEP 2163.02). Based on the information given in the specification as cited herein, one of skill in the art could easily visualize a polynucleotide within the metes and bounds of the present claims.

Why Appellant believes the Claims to be Separately Patentable:

Claim 1

Independent claim 1, part a) is supported in the specification on page 4, lines 25 and 26 and by the disclosure of SEQ ID NO:1 which is a maize GDP- mannose

pyrophosphorylase. Claim 1, part a) is further supported in the specification on page 5, lines 17 through line 30; particularly line 26 which states: " Preferably, the GDP-mannose pyrophosphorylase is native to maize or a leguminous plant. By native to maize or a leguminous plant is meant that the GDP-mannose pyrophosphorylase may be present in a naturally occurring or cultivated species of maize or a leguminous plant. "

Part b) of claim 1 is supported by the disclosure of SEQ ID NO:2 in the sequence listing.

Part c) of claim 1 is supported by the disclosure of SEQ ID NO:1 in the sequence listing.

Part d) of claim 1 is supported by the disclosure in the specification on page 12, lines 19 through 29 of the method of alignment used to determine percent identity. Of particular relevance are lines 24 through 27 which state: "For the purposes of the instant invention, sequence identity is determined by the GAP program, version 10 in the Wisconsin Genetics Software Package, Genetics Computer Groups (GCG) (575 Science Drive, Madison, Wisconsin) using the default settings."

Part e) of claim 1 is supported on page 14, lines 27-29 which state:" . In one embodiment, a tissue-specific and inducible promoter is used to drive expression of an antisense RNA to a GDP-mannose pyrophosphorylase mRNA."

Thus, claim 1 is adequately described in terms of structure and the function correlated with that structure.

Claim 3

Dependent claim 3 is further supported by the sequence listing which states the sequence was isolated from maize. Further support is found in Example 1 on page 18, lines 18 through 27 which provides a working example of GDP-mannose pyrophosphorylase nucleotide sequence isolation from maize

Claim 4

Dependent claim 4 is further supported in the specification on page 5, lines 26 and 27 which state: "Preferably, the GDP- mannose pyrophosphorylase is native to maize or a leguminous plant." Those of skill in the art would understand "beans and peas" to be inherent in the set of leguminous plants.

Claim 5

Claim 5 finds support in the specification beginning on page 13, line 6, continuing through page 14, line 25 which discusses the use of the claimed sequences with various promoters to drive expression in plants.

It is believed all elements of claim 5 are supported by the specification or are conventional in the art.

Claim 7

Dependent claim 7 finds further support in Example 1, on page 18 of the specification which describes isolating a maize GDP-mannose pyrophosphorylase and the construction of an expression cassette.

Claim 8

Dependent claim 8 is further supported on page 16, line 25 of the specification which states: "Leguminous plants include beans and peas."

Claim 9

Dependent claim 9 is further supported in the specification on page 14, lines 1 through 4 which discuss tissue-specific promoters.

Claim 10

Dependent claim 10 is further supported in the specification on page 14, lines 5 through 9 which discuss seed-preferred promoters.

Claim 11

Dependent claim 11 is further supported in the specification on page 14, lines 9 through 25 which cite the particular tissue-specific promoters of the claim.

Claim 12

Dependent claim 12 is further supported in the specification on page 13, lines 8 through 29 which discusses and cites constitutive promoters.

Claim 13

Dependent claim 13 is supported particularly on page 13, lines 28 and 29 which cites the Scp1 promoter.

Claim 23

Independent claim 23 is supported in the specification on page 16, lines 19 through 21 which state: "The sequences of the present invention can be used to transform or transfect any plant. In this manner, genetically modified [i.e., recombinant] plants, plant cells ... and the like can be obtained."

It is believed all elements of claim 5 are supported by the specification or are known to those of skill in the art.

Claim 24

Dependent claim 24 is further supported by original claim 1 and the support cited herein for claim 1.

Claim 32

Independent claim 32 is supported in the specification on page 16 beginning on line 19, through page 17, line 27 which discusses plant transformation/transfection (i.e., stably incorporating a nucleotide sequence into a plant genome). Further support is found in Example 2 beginning on page 19. Antisense sequences find support on page 14, lines 27-29. The "sequences operably linked to a promoter that drives expression in a plant" (i.e., an expression cassette or expression vector) are supported in the specification on pages 13, line 6, continuing through page 14, line 25, which discusses the use of the claimed sequences with various promoters to drive expression in plants.

It is believed one of skill in the art would easily envisage the transformed plant that would result by: "having stably incorporated into its genome at least one nucleotide sequence encoding a GDP-mannose pyrophosphorylase or an antisense sequence thereof; said sequence operably linked to a promoter that drives expression in a plant" as recited in claim 32.

Claim 33

Dependent claim 33 is further supported by original claim 1 and the support recited herein for claim 1.

Claim 41

Dependent claim 41 is further supported in the specification on page 16, lines 28 through 30, which state: "Transformation protocols as well as protocols for introducing nucleotide sequences into plants may vary depending on the type of plant or plant cell, i.e. *monocot* or dicot, targeted for transformation." (italics inserted).

Claim 42

Dependent claim 42 is further supported by original claim 42 and in the specification on page 16, line 23.

Claim 43

Dependent claim 43 is further supported in the specification on page 16, lines 28 through 30, which states: "Transformation protocols as well as protocols for introducing nucleotide sequences into plants may vary depending on the type of plant or plant cell, i.e. monocot or *dicot*, targeted for transformation." (italics inserted).

Claim 44

Dependent claim 44 is supported on page 16, lines 23 and 24 which recite the transformed dicots of the claim.

Claim 45

Dependent claim 45 is further supported in the specification on page 16, line 20 which describes genetically modified (i.e., transformed) seed, as well as lines 23 and 24 which recite the plants of claim 44.

The First Paragraph of Section 112 Rejection of Claims 1, 3-5, 7-13, 23, 24, 32, 33, and 41-45 for scope of enablement

In rejecting claims 1, 3-5, 7-13, 23, 24, 32, 33, and 41-45 under §112, first paragraph for scope of enablement, the Examiner states: "... claim 1 is drawn ... also to any maize or leguminous plant GDP-mannose phryphosphorylase [sic]. The rejection remains over any such sequence ... since it would require more than routine experimentation to discover any such sequence having the claimed functions."

As stated in the previous responses, the specification contains sufficient support that one of skill in the art could isolate, and ascertain the function, of the claimed sequences without undue experimentation.

The disclosed sequences, used in concert with the methods disclosed in the specification clearly enable one skilled in the art to isolate sequences within the scope of claim 1. The specification states on page 8, beginning on line 23: "... the sequences of the invention can be used to isolate corresponding sequences in other organisms, particularly other plants. In this manner, methods such as PCR, hybridization, and the like can be used to identify such sequences having substantial sequence similarity to the sequences of the invention" The specification goes on to cite and describe standard protocols for such isolation methods through the end of page 12.

Once putative sequences are isolated, a standard assay, known in the art at the time the application was filed, can be used to confirm GDP- mannose pyrophosphorylase function. Such an assay is cited in the specification on page 17, beginning on line 28.

The Examiner's assertion that "more than routine" experimentation would be required to practice the scope of claim 1 fails to take into account the routine nature of screening for results that is the heart of the biotechnological arts. The Examiner has confused repetitive procedure with undue experimentation.

Why Appellant believes the Claims to be Separately Patentable:

Claim 1

Independent claim 1 is enabled by the disclosure provided in Example 1, page 18, lines 18 through 27 of the specification, which describes the manner in which the maize GDP- mannose pyrophosphorylase nucleotide sequence was isolated, and sequenced and the manner in which the amino acid sequence (reading

frame) was determined. Part d) of claim 1 is enabled on page 12, lines 19 through 29 which describes the method of alignment used. Part e) of claim 1 is enabled on page 5, lines 11 and 12, and by the knowledge of those of skill in the art.

It is believed the disclosure, when filed, contained sufficient information regarding the subject matter of claim 1 so as to enable one of skill in the art to make and use the claimed invention.

Claim 3

Dependent claim 3 is likewise enabled by the disclosure of Example 1, page 18, lines 18 through 27 of the specification, which describes the isolation of GDP- mannose pyrophosphorylase from maize tissue.

Claim 4

Dependent claim 4 is enabled by the statement on page 5, lines 26 and 27 which state: "Preferably, the GDP- mannose pyrophosphorylase is native to maize or a leguminous plant." Those of skill in the art would understand "beans and peas" to be inherent in the set of leguminous plants.

Claim 5

Claim 5 is enabled by the disclosure of Example 1, page 18, lines 27 through 30 and further on page 19, lines 1 and 2 which describe the construction of an expression cassette. "... comprising a nucleotide sequence of claim 1, wherein said nucleotide sequence is operably linked to a promoter that drives expression in a plant." Further enablement is found on pages 13 and 14 of the specification (beginning on line 6 of page 13, through line 25 on page 14), which discusses the use of the claimed sequences with various promoters to drive expression in plants.

Claim 7

Dependent claim 7 is likewise enabled by the disclosure in Example 1, page 18, lines 18 and 19 which state that the source of the isolated GDP- mannose pyrophosphorylase was maize tissue.

Claim 8

Dependent claim 8 is enabled by the disclosure on page 5, lines 26 and 27 which state: "Preferably, the GDP- mannose pyrophosphorylase is native to maize or a leguminous plant." Those of skill in the art would understand "beans and peas" to be inherent in the set of leguminous plants.

Claim 9

Dependent claim 9 is enabled by the disclosure on page 14, lines 1 through 4 of the specification, of tissue-specific promoters.

Claim 10

Dependent claim 10 is enabled by the disclosure on page 14, lines 5 through 9 of the specification, of seed-preferred promoters.

Claim 11

Dependent claim 11 is enabled by the disclosure on page 14, lines 9 through 25 of the specification which cites particular tissue-specific promoters.

Claim 12

Dependent claim 12 is enabled by the disclosure on page 13, lines 8 through 29 of the specification which discusses and cites constitutive promoters.

Claim 13

Dependent claim 13 is enabled on page 13, lines 28 and 29 which cites the Scp1 promoter.

Claim 23

Independent claim 23 is enabled in the specification by Example 2 beginning on page 19. Example 2 describes maize callus cells which have been transformed with "... at least one nucleotide sequence encoding a GDP-mannose pyrophosphorylase or an antisense RNA thereof; wherein said nucleotide sequence is operably linked to a promoter that drives expression in a plant."

Claim 24

Dependent claim 24 is enabled by the disclosures cited herein for claim 1 and on page 16 of the specification lines 19 through 21 which state: "The sequences of the present invention can be used to transform or transfect any plant. In this manner, genetically modified [i.e., recombinant] plants, plant cells ... and the like can be obtained."

Claim 32

Independent claim 32 is enabled in the specification by the section of Example 2 beginning on page 20: "Subsequent Treatment" which discloses a manner of regenerating plants transformed with "... at least one nucleotide sequence encoding a GDP-mannose pyrophosphorylase or an antisense sequence thereof; said sequence operably linked to a promoter that drives expression in a plant."

Claim 33

Dependent claim 33 is enabled by the disclosures cited herein for claim 1 and by Example 2 in the specification beginning on page 20.

Claim 41

Dependent claim 41 is enabled on pages 16 and 17 of the specification which disclose methods of transformation for monocots: particularly on page 17, lines 14 through 19.

Claim 42

Dependent claim 42 is enabled on page 16 of the specification, lines 28 through 30.

Claim 43

Dependent claim 43 is enabled on pages 16 and 17 of the specification which disclose methods of transformation for dicots: particularly on page 17, lines 11 through 14.

Claim 44

Dependent claim 44 is enabled in the specification on pages 16 and 17 as cited herein for claim 43 and by knowledge of those of skill in the art at the time of filing.

Claim 45

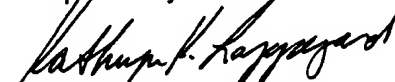
Dependent claim 45 is enabled in the specification on page 16, line 20 which describes genetically modified (i.e., transformed) seed and for the enablement provided for the recited transformed plants, as one of skill in the art understands that seeds are an inherent part of the recited plants.

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CONCLUSION

On the basis of the above amendments and remarks, reconsideration of the application and it's allowance are respectfully requested.

Respectfully submitted,



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APPENDIX

Claims on Appeal

1. An isolated nucleotide sequence selected from the group consisting of:
 - a) a nucleotide sequence encoding a maize or leguminous plant GDP-mannose pyrophosphorylase;
 - b) a nucleotide sequence encoding the amino acid sequence of SEQ ID NO:2;
 - c) a nucleotide sequence set forth in SEQ ID NO:1;
 - d) a nucleotide sequence having at least 90% identity to a nucleotide sequence of a), b), or c); and
 - e) a nucleotide sequence encoding an antisense RNA of a nucleotide sequence of a), b), c), or d.
3. The isolated nucleotide sequence of claim 1, wherein said GDP-mannose is native to maize.
4. The isolated nucleotide sequence of claim 1, wherein said leguminous plant is selected from the group consisting of beans and peas.
5. An expression cassette comprising a nucleotide sequence of claim 1, wherein said nucleotide sequence is operably linked to a promoter that drives expression in a plant.
7. The expression cassette of claim 5, wherein said GDP-mannose pyrophosphorylase is native to maize.

8. The expression cassette of claim 5, wherein said leguminous plant is selected from the group consisting of beans and peas.
9. The expression cassette of claim 5, wherein said promoter is a tissue-specific promoter.
10. The expression cassette of claim 9, wherein said promoter is a seed-preferred promoter.
11. The expression cassette of claim 10, wherein said promoter is selected from the group of promoters consisting of: cim1, cZ19B1, gama-zein, glob-1 and phaseolin.
12. The expression cassette of claim 5, wherein said promoter is a constitutive promoter.
13. The expression cassette of claim 12, wherein said promoter is a ubiquitin or a Scp1 promoter.
23. A recombinant plant cell having stably incorporated into its genome at least one nucleotide sequence encoding a GDP-mannose pyrophosphorylase or an antisense RNA thereof; wherein said nucleotide sequence is operably linked to a promoter that drives expression in a plant.
24. The plant cell of claim 23, wherein said nucleotide sequence is selected from the group consisting of:
 - a) a nucleotide sequence encoding a GDP-mannose pyrophosphorylase that is native to maize or a leguminous plant;

- b) a nucleotide sequence encoding the amino acid sequence of SEQ ID NO:2;
 - c) a nucleotide sequence set forth in SEQ ID NO:1;
 - d) a nucleotide sequence having at least 90% identity to a nucleotide sequence of a), b), or c); and
 - e) a nucleotide sequence encoding an antisense RNA of a nucleotide sequence of a), b), c), or d.
32. A transformed plant having stably incorporated into its genome at least one nucleotide sequence encoding a GDP-mannose pyrophosphorylase or an antisense sequence thereof; said sequence operably linked to a promoter that drives expression in a plant.
33. The plant of claim 32, wherein said nucleotide sequence is selected from the group consisting of:
- a) a nucleotide sequence encoding a GDP-mannose pyrophosphorylase that is native to maize or a leguminous plant;
 - b) a nucleotide sequence encoding the amino acid sequence of SEQ ID NO:2;
 - c) a nucleotide sequence set forth in SEQ ID NO:1;
 - d) a nucleotide sequence having at least 90% identity to a nucleotide sequence of a), b), or c); and
 - e) a nucleotide sequence encoding an antisense RNA of a nucleotide sequence of a), b), c), or d.
41. The plant of claim 32 wherein said plant is a monocot.

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42. The plant of claim 32 wherein said monocot is maize, wheat, rice, barley, sorghum, or rye.
43. The plant of any of 32 wherein said plant is a dicot.
44. The plant of claim 32 wherein said dicot is soybean, Brassica, sunflower, alfalfa, or safflower.
45. The seed of the plant of claim 32.